DEVICE FOR THE PRODUCTION OF ANASTOMOSES BETWEEN HOLLOW ORGANS

RELATED U.S. APPLICATIONS

Not applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

REFERENCE TO MICROFICHE APPENDIX

Not applicable.

FIELD OF THE INVENTION

[0001] The invention relates to a device for the production of anastomoses between hollow organs, with an inner sleeve to be mounted around the end of the first hollow organ and with an outer sleeve to be mounted around the end of the second hollow organ after the latter end has been arranged over the end of the first hollow organ, which has been turned inside out over the inner sleeve, the inner and outer sleeves being made separable so that they can be removed after anastomosis formation has been completed.

BACKGROUND OF THE INVENTION

[0002] The term "hollow organs" denotes, for example, blood vessels as well as the structures through which urine flows and the hollow organs of the digestive tract etc., and the

need to connect such organs arises very often in surgery. In all such cases a distinction is made between end-to-end anastomoses, in which two ends of two hollow organs are connected to one another, and end-to-side anastomoses, in which the end of one hollow organ is put into communication with a second organ at the side of the latter.

[0003] For connecting hollow organs the predominant techniques involve stitching, such that a plurality of sutures create the junction. Apart from the great surgical effort involved here, in particular in the case of small vessels, the region of the sutures is frequently affected by complications such as thromboses, in the case of blood vessels.

[0004] In addition to the stitching techniques, there also exist adhesive techniques, for instance employing fibrin adhesives, which allow anastomoses to be formed more rapidly than is the case with sutures, and furthermore the resulting connections are more elastic. It is disadvantageous here that many adhesives are thrombogenic and toxic, and hence are not to be recommended, in particular for vascular anastomoses.

[0005] In addition to the above-mentioned stitching and adhesive techniques, clamping techniques are used in which specially shaped clamps create the vessel connections; these can be attached in less time than it takes to stitch conventional sutures. To assist the production of anastomoses, since the beginning of the 20th Century various accessories such as rings, "cuffs" or stents have been used, by means of which secure, rapid and reliable connections can be created. The disadvantage here is that these accessories ordinarily remain in place after the organs have been connected, and then can elicit rejection responses or, in the case of vascular anastomoses, can increase the risk of thromboses. To avoid these problems it has been specified

that these accessories be made of materials that disintegrate after a certain time, as described for instance in the document DE 44 17 528 A1. The document EP 0 554 990 B1 describes an apparatus of the kind cited above for constructing anastomoses in which the hollow organs are connected by means of sutures and clamps. The sleeves used to promote anastomosis formation can be made separable, so that they can be removed after anastomosis formation has been completed. Subsequently, however, the sutures and clamps still remain in the hollow organ, where they can increase the risk of thrombosis if the anastomosed structures are vessels.

[0006] Laser energy can also be employed to connect biological tissue: when it is applied to hollow organs that are to be connected, the resultant heating causes the tissue of the organs to become fused. Anastomoses thus created by laser exhibit a less pronounced foreign-body reaction. With respect to thrombogenesis, however, no advantage of this approach has yet been demonstrated. Furthermore, the temperatures produced by a laser can also cause destruction of the tissue. An apparatus for fusing biological tissue by means of laser energy is described, for example in the document EP 480 293 A1.

[0007] In addition to the production of heat by means of lasers, methods also exist in which local temperature elevations for the purpose of fusing biological tissue are produced by means of electrical current. If the tissue temperature remains below a value of about 100°C, the result is that the substance of the cells coagulates and their protein structures stick to one another in a disorderly manner, so that tissues can become fused. This kind of seamless method of producing vessel anastomosis has been implemented, for example, by means of wire rings disposed aroung the ends of the vessels, with the supplementary use of fibrin adhesives (E. Wintermantel: The thermic vascular

anastomosis (TVA). A new nonsuture method. I. History, Instruments and microsurgical technique; Acta Neurochir. 1981; 56 (1-2): 5-24). The tissue coagulation was produced by imposing several brief current pulses. The wire rings through which the current was introduced, however, were left in place at the anastomosis site. A device for the electrothermal implementation of tissue connections has also been described in the document WO 98/38935 A1.

[0008] Another device for the suture-free production of end-to-end anastomoses is described in the document WO 99/63910 A1; here the inserted stent remains in the vessel after anastomosis formation is complete. In this case substantially cylindrical transplants made of metal, plastic or the like are connected by way of likewise cylindrical elements to the ends of the hollow organs or vessels that are to be connected. Connection of the elements to the vessel wall can be brought about, for example, by means of high-frequency current or conventionally, by inserting stitches. This operation always leaves elements in the vessel, which in the case of blood vessels increases the risk of thrombosis. Although this risk can be reduced by applying coatings of heparin or thrombolytic substances, it can never be entirely excluded.

BRIEF SUMMARY OF THE INVENTION

[0009] The object of the present invention is to create a device as cited above by means of which rapidly formed, but also reliable and permanent anastomoses of biological hollow organs can be produced. In addition the device is intended to be constructed in the simplest and most economical manner, and to present no danger of rejection and involve the lowest possible risk of thrombosis, in the case of blood vessels. The disadvantages of the state of the art are to be avoided, or at least reduced.

[0010] The problem posed in accordance with the invention is solved by the fact that the inner sleeve and the outer sleeve comprise electrically conductive materials that can be connected to an external current or voltage source in order to apply a current or a voltage to the contact surfaces, so as to induce electrocoagulation of the hollow organs that are to be connected. The device in accordance with the invention combines the advantages of employing removable accessories for producing anastomoses, i.e. objects that are eliminated when the process of anastomosis has been completed, with a tissue bonding induced by electrocoagulation, which provides a particularly gentle but also secure and permanent connection of the hollow organs. The term "sleeve" denotes tubular as well as ring-shaped elements, which are positioned around the hollow organs that are to be connected and are as closely apposed thereto as possible. By means of the device described here, anastomoses can be produced without leaving any foreign bodies in place. As a result, in the case of blood vessels the risk of thrombosis is considerably reduced. It is possible for the inner and/or the outer sleeve to be made of the electrically conductive material itself. In this case, for instance, stainless steel or platinum can be used as electrically conductive material or as a coating of the sleeve, in particular where insertion into humans is concerned. It is also possible to dispose on the outer surface of the inner sleeve and/or the inner surface of the outer sleeve at least one contact surface made of electrically conductive material.

[0011] In this arrangement, the contact surfaces are preferably provided with suitable connecting wires, to provide a connection to the external current or voltage sources.

[0012] In order to achieve an annular fusion seam with no gaps, the contact surfaces on the inner sleeve and the outer sleeve are preferably circumferentially arranged. To improve the connection between the hollow organs, it is also possible for several circumferential contact surfaces to be disposed on the inner and outer sleeves, or else there can be a single, broad contact surface on the inner sleeve and several narrow contact surfaces on the outer sleeve.

[0013] The separability of the inner and/or outer sleeve can be implemented, according to another characteristic of the invention, by means of preferably spring-loaded pivotable parts. This can be achieved by an articulated linkage between the two sleeve parts or by disposing the sleeve parts on forceps- or clamp-like instruments, as is known per se, or by similar means.

[0014] The sleeve parts can comprise catch elements that can become interlocked when in the closed position, in order to provide a solid, continuous sleeve during the period of anastomosis formation.

[0015] The separability of the sleeves can also be achieved by providing predetermined breaking sites at which they can be broken apart when anastomosis formation is complete, so that the sleeves can be removed from the connected hollow organs, leaving the tissue junction free of foreign bodies. The breaking sites can be formed by axial grooves along the sleeves, which reduce the thickness of the material and make it easy to break the sleeve open. Similarly, the breaking sites can take the form of readily separable adhesive joints. In particular the outer sleeve can be formed in an especially simple manner by a wire arranged in the form of a loop, which is closely apposed to the outer surface of the hollow organs to be connected and by way of which an electrocoagulation current is imposed. Such a wire loop is also particularly

easy to adjust to the circumference of the particular hollow organs to be connected. By providing the inner sleeve with fitting elements and the outer sleeve with elements having a complementary configuration, so that the two sets of elements can be fitted into one another during coagulation, it is possible to arrange the two sleeves in an orderly manner, so as to produce an orderly fusion of the hollow organs. Fitting elements of this kind can be formed by circumferential grooves on the sleeves.

[0016] The inner and/or outer sleeve can be made of plastic, for example polyethylene. This material is especially suitable for the cited purposes.

[0017] As mentioned above, the contact surfaces of the sleeves can consist of stainless steel or also of platinum.

[0018] In order to obtain information about the effect of the electrocoagulation, an impedance-measuring device can be disposed between the contact surfaces of the sleeves. By measuring the tissue impedance, the fusion of the hollow organs can be suitably monitored.

[0019] Information about the quality of coagulation can also be obtained by way of a temperature sensor disposed at the inner sleeve and/or the outer sleeve; thus the occurrence of unacceptably high tissue temperatures that might, for example, cause the cells to be destroyed, is indicated and can subsequently be prevented.

[0020] For the purpose of controlling the current or voltage introduced by way of the inner or outer sleeve, the current or voltage source can be connected to a control means.

[0021] In order to control the electrocoagulation time, the control means can comprise a timer that specifies the

duration of the current or voltage pulse during the electrocoagulation process.

[0022] To construct a control circuit the impedance-measuring device and/or the temperature sensor can be connected to the current or voltage source or to a control means, if present, so that the process of hollow-organ fusion can take place under precisely prescribed conditions.

[0023] Since most hollow organs that need to be connected have a substantially cylindrical cross section, the sleeves are also substantially cylindrical in cross section. Naturally, a differently shaped cross section is likewise possible for special applications.

[0024] The present invention will now be explained further with reference to preferred exemplary embodiments and to the drawings, as follows.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0025] Fig. 1 shows a cross section through an end-to-end anastomosis for which the device in accordance with the invention is being used;

[0026] Fig. 2 is a perspective view of an embodiment of the inner sleeve;

[0027] Fig. 3 is a perspective view of an embodiment of the outer sleeve;

[0028] Figs. 4a to 4h are perspective views of an end-to-end vascular anastomosis as it is being produced; Figs. 5a and 5b show an embodiment of an inner sleeve prior to use and after separation;

[0029] Fig. 6 is a perspective view of another embodiment of an inner sleeve; and

[0030] Fig. 7 shows a cross section through an end-to-end anastomosis for which another embodiment of the device in accordance with the invention is being used.

DETAILED DESCRIPTION OF THE INVENTION

[0031] Fig. 1 shows a cross section through an end-to-end anastomosis of two hollow organs 1, 2, for example two arteries. Over the end of the hollow organ 1 a sleeve 3 has been pushed, and the end of the hollow organ 1 has been folded back over this sleeve 3. Then the end of the hollow organ 2 to be connected thereto is pushed over the inverted end of the first hollow organ 1, which now encloses the inner sleeve 3, and finally the outer sleeve 4 is placed over the inner sleeve 3. So that the sleeves 3, 4 can be removed after anastomosis is complete, each is designed to be separable. In accordance with the invention the inner sleeve 3 and the outer sleeve 4 both incorporate electrically conductive material, which preferably takes the form of corresponding contact surfaces 5, 6 in the sleeves 3, 4. It is likewise possible for the sleeves 3, 4 as a whole to be made of electrically conductive material. The contact surfaces 5, 6 are preferably disposed circumferentially around the sleeves 3, 4, so that after coagulation has been completed a continuous, secure connection between the hollow organs 1 and 2 will be achieved. The contact surfaces 5, 6 are connected by way of corresponding leads 7, 8 to an external current or voltage source 9, which applies an appropriate current or voltage to the contact surfaces 5, 6 for electrocoagulation of the hollow organs 1, 2 that are to be connected. To control the applied current or voltage, a control means 10 can be disposed between the current or voltage source 9 and the contact surfaces 5, 6 on the sleeves 3, 4, which can also

include a time-switch 11 to determine the duration of the current or voltage pulses, or can be connected to such a time-switch 11. For measurement of the impedance of the tissue between the contact surfaces 5, 6 there can be connected to the leads 7, 8 a corresponding impedance-measuring apparatus 12, which in turn can be connected to the current or voltage source 9 or to the control device 10 to control the current or the voltage during the electrocoagulation. To monitor the temperature during electrocoagulation, in the inner sleeve 3 and/or the outer sleeve 4 can be disposed a temperature sensor 13, which is preferably connected directly to the current or voltage source 9 or to the control means 10 for regulating the connection process. With the device in accordance with the invention it is possible to create an optimal connection by employing the sleeves 3, 4 (which are known per se) and using electrical energy to fuse the tissues of the hollow organs 1, 2. After the anastomosis has been completed the sleeves 3, 4 are removed, so that no foreign bodies remain and a seamless connection between the hollow organs 1, 2 results.

[0032] Figure 2 shows in perspective an inner sleeve 3 consisting of two pivotable components 3', 3" that are connected to the ends of a correspondingly shaped clamp 14 made of spring-steel wire. By pressing on the limbs of the clamp 14, the components 3' and 3" of the sleeve can be swiveled apart, and the sleeve 3 can be placed over the hollow organ 1 and, after anastomosis formation is complete, removed again. Here the clamp 14 makes electrically conductive connection with the contact surface 5 of the sleeve 3, by way of corresponding connector pieces 15, and the application of current is achieved directly by way of the clamp 14.

[0033] Figure 3 shows in perspective an embodiment of the outer sleeve 4 consisting of two parts 4', 4", which likewise

are pivotably connected to one another by way of a clamp 14 made of spring-steel wire. Here, again, the contact surfaces 6 of the sleeve 4 are connected to the clamp 14 so as to be electrically conductive, and the connection to the current or voltage source 9 is implemented by way of the clamp 14.

[0034] Figures 4a to 4h show the steps to be taken in creating an end-to-end anastomosis of two hollow organs 1, 2, such as blood vessels. In the first step the sleeve 3 is pushed over the end of the hollow organ 1, or else the parts 3', 3" of the sleeve 3 are rotated apart and, having been placed over the hollow organ 1 from the side, are closed again. As shown in Fig. 4b, the end of the hollow organ 1 is folded back over the sleeve 3. According to Fig. 4c the end of the second hollow organ 2 is pushed over the end of the first hollow organ 1, which has been inverted over the inner sleeve 3, so that the situation shown in Fig. 4d results. Thereafter, as shown in Fig. 4e, by rotation of the components 4' and 4" of the outer sleeve 4, the sleeve 4 is positioned axially so as to enclose the circumference of the hollow organ 2, overlying the sleeve 3. As shown in Fig. 4f, between the contact surfaces 5, 6 of the sleeves 3, 4 an electrical current or an electrical voltage with prespecified pulse shape, amplitude, duration and frequency is applied, as a result of which the cellular substance coagulates and brings about fusion of the protein structures comprising the tissue of the hollow organs 1 and 2. After removal of the outer sleeve 4, the resulting anastomosis is as shown in Fig. 4g, in which can be seen the resulting ring-shaped circumferential fusion seam 16. Thereafter the sleeve 3 is removed by first shifting it axially and then separating the components 3' and 3". The end result is an anastomosis as shown in Fig. 4h, which is free of all the accessories used during the formation of the anastomosis. The arrows in the hollow organs 1 and 2 indicate, for example in the case of a blood vessel, the possible direction of blood flow.

[0035] Figures 5a and 5b show an embodiment of an inner sleeve 3 with an annular contact surface 5, which is connected to an electrical supply cable 7. The sleeve 3 has on its inner surface predefined breaking sites 17 in the form of axially oriented grooves, which allow the sleeve 3 to be broken apart after the anastomosis is completed, so that the two separated components 3', 3" can be removed from the hollow organ 1 (Fig. 5b). Instead of such predefined breaking sites 17 it is possible for two initially separate components 3', 3" of the sleeve 3 to be glued together and subsequently separated.

[0036] Fig. 6 shows another embodiment of a sleeve 3, in which two annular contact surfaces 5 are electrically connected to one another by way of appropriate connecting elements 18. The components 3', 3" of the sleeve 3 can additionally be provided with catch elements 19, 20 that hold the components 3', 3" together when the sleeve 3 is in the closed position, but nevertheless make it possible for the components 3', 3" to be easily separated.

[0037] Fig. 7, finally, shows another embodiment of the device in accordance with the invention in cross section; in this case fitting elements 21, for example in the form of a circumferential groove, are disposed on the inner sleeve 3, and the outer sleeve 4 is provided with corresponding fitting elements 22 with a complementary shape, for example a likewise circumferential groove, which enable exact positioning of the sleeves 3, 4 with respect to one another.

[0038] The invention is not restricted to the exemplary embodiments presented here, and can be modified within the scope of the claims.